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	005072	A. BUILDING: _____ B. WING _____	04/20/2016

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FRANCISCAN HEALTH RENSSELAER, INC	1104 E GRACE ST RENSSELAER, IN 47978

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S 000	INITIAL COMMENTS This visit was for a State hospital licensure survey. Dates: 4/18/2016 to 4/20/2016 Facility Number: 005072 QA: cjl 05/11/16	S 000		
S 320	410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(c)(6)(G) (c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive officer develops policies and programs for the following: (G) Providing employee health services and a post offer physical examination, in consultation with the infection control committee. This RULE is not met as evidenced by: Based on document review and interview, the governing board failed to ensure the provision of a post offer physical examination in consultation with the infection control committee and in accordance with facility policy and procedure for 10 of 23 (N5, N12-N14 and N16-N21) personnel records reviewed. Findings:	S 320		5/31/16

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S 320	Continued From page 1 1. Policy #AM-IV-1, Employee Health Requirements, revised/reapproved on 8/15/13 indicated on pg. 1, under Employment Requirements, point 1. c., physical examinations are required prior to Personnel Orientation for all employees beginning May 4, 2010...the examination will be performed by a Family Nurse Practitioner (FNP) at no expense to the employee. 2. Review of personnel records confirmed personnel: A. N5, was hired 12/13 and lacked documentation of a post offer physical examination. B. N12, was hired 12/20/15 and lacked documentation of a post offer physical examination. C. N13, was hired 9/1/15 and lacked documentation of a post offer physical examination. D. N14, was hired 9/1/15 and lacked documentation of a post offer physical examination. E. N16, was hired 9/1/15 and lacked documentation of a post offer physical examination. F. N17, was hired 9/1/15 and lacked documentation of a post offer physical examination. G. N18, was hired 9/1/15 and lacked documentation of a post offer physical examination. H. N19, was hired 12/20/15 and lacked documentation of a post offer physical examination. I. N20, was hired 9/1/15 and lacked documentation of a post offer physical examination. J. N21, was hired 12/20/15 and lacked	S 320		

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S 320	Continued From page 2 documentation of a post offer physical examination. 3. Staff 8 (Infection Prevention & Employee Health) was interviewed on 4/19/16 at approximately 1010 hours and confirmed only an Employee Medical History Form is being completed and signed by a Registered Nurse. Post offer physical examinations are not being completed for personnel hired beginning 5/4/10 as required per facility policy and procedure.	S 320		
S 406	410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2(a)(1) (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (1) All services, including services furnished by a contractor. This RULE is not met as evidenced by: Based on document review and interview, the hospital failed to ensure six (Electroencephalography, Pediatrics, Infusion Therapy, Biohazard Waste Hauler, Laundry and Security) of six services were evaluated through the quality assessment and improvement (QA&I)	S 406		6/3/16

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S 406	Continued From page 3 program. Findings included: 1. Review of the Franciscan Healthcare Rensselaer Quality Assurance & Performance Improvement Program Plan indicated "The Quality Plan shall be a coordinated, comprehensive and continuous effort of the Hospital Board of Trustees, Medical Staff, administration, departments and employees to monitor and improve the performance of all care and services provided at the Hospital." The QAPI Plan was last reviewed 11/6/2014. 2. Review of the Hospital Quality and Patient Safety committee dashboards and minutes for 2015 indicated the documents that were provided lacked documentation of evaluating or addressing the following services: Electroencephalography, Pediatrics, Infusion Therapy, Biohazard Waste Hauler, Laundry and Security. 3. In interview at 2:30 PM on 4/19/20176, staff member #6 (Director Quality Management) confirmed all the above and no other documentation was provided prior to exit.	S 406		
S 418	410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2(b)(1)(2) (b) The hospital shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:	S 418		6/3/16

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S 418	Continued From page 4 (1) The action shall be documented. (2) The outcome of the action shall be documented as to its effectiveness, continued follow-up and impact on patient care. This RULE is not met as evidenced by: Based on document review and interview, the hospital failed to document an action plan to address the opportunities for improvement for 5 (blood bank, dietary, nursing medical/surgical, anewthesia and infection control [Wound]) of 5 services in the hospital's quality assessment and improvement (QA&I) program. Findings included: 1. Review of the Franciscan Healthcare Rensselaer Quality Assurance & Performance Improvement Program Plan indicated "All departments and teams are required to submit performance indicator information in a timely manner, at least quarterly." The QAPI Plan was last reviewed 11/6/2014. 2. Review of 5 services of the hospital's QAPI program dashboards indicated there was no evidence of written action plans for areas that fell short of their goals. A. Blood Bank - Charts meeting transfusion criteria targeted goal was 100% and in the 4th quarter of 2015, the hospital only met 96% of the target. The department dashboards lacked documented remedial action to address deficiencies. B. Dietary - All food safety & sanitation audit	S 418		

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S 418	Continued From page 5 monitors are being practiced. Criteria targeted goal was 100% and in the 4th quarter of 2015, the hospital only met 87% of the target. The department dashboards lacked documented remedial action to address deficiencies. C. Nursing Medical/Surgical - Medication education aligns with primary diagnosis criteria targeted goal was 100% and in the 4th quarter of 2015, the hospital only met 68% of the target. The department dashboards lacked documented remedial action to address deficiencies. D. Anesthesia - Pre/Post assessment completed and signed criteria targeted goal was 98% and in the 1st quarter of 2016, the hospital only met 80% of the target. The department dashboards lacked documented remedial action to address deficiencies. E. Infection Control (Wound) - Documented on admitted from Emergency Department criteria targeted goal was 100% and in the 4th quarter of 2015, the hospital only met 17% of the target. The department dashboards lacked documented remedial action to address deficiencies. 3. In interview at 2:30 PM on 4/19/20176, staff member #6 (Director Quality Management) confirmed all the above and no other documentation was provided prior to exit.	S 418		
S 754	410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4(f)(5) (f) All inpatient records, except those in subsections (g), shall	S 754		5/16/16

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S 754	Continued From page 6 document and contain, but not be limited to, the following: (5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure properly executed informed consent for 2 of 4 (9 and 12) surgical patient medical records reviewed. Findings: 1. Policy #NS-29, Health Information Management: Consent to Operation(s), Anesthetics, and Other Medical Services, revised/reapproval 2/12/16, indicated on pg. 1, under Procedure section, "To be filled out for all inpatients and outpatients who are to have any major or minor surgery. Must be signed before surgery...date and time consent obtained." 2. Review of patient medical records confirmed patient: A. 9 underwent a surgical procedure on 1/29/16 and Surgical Consent lacked the time of the physician's signature. B. 12 underwent a surgical procedure on 11/18/15 and Surgical Consent lacked the time of the physician's signature.	S 754		

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S 754	Continued From page 7 3. Staff 19 (Health Information Management) was interviewed on 4/18/16 at approximately --1300 hours, and confirmed the above-mentioned patients lacked the time the physician signed the Surgical Consent and these forms need to be signed, dated, and timed by the patient (if able) and the witness and the physician prior to the start of the procedure.	S 754		
S1022	410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(B) (d) Written policies and procedures shall be developed and implemented that include the following: (2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following: (B) Appropriate storage conditions. This RULE is not met as evidenced by: Based on observation, document review and interview, the facility failed to ensure appropriate storage conditions for medications according to facility policy and procedure for 1 of 7 (Surgery Department) areas toured. Findings: 1. Policy #PH-41, High Risk or High Alert Medications, revised/reapproved on 3/31/13 indicated on pg:	S1022		4/21/16

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S1022	Continued From page 8 A. 2, under Procedure section, points 4.iv. and v., employees will be mindful of high-alert medications. These medications will be sequestered and separated from the general medication inventory in a system that would reduce errors. Pharmacy will apply special auxiliary (High-alert) warning labels on the storage bins containing high-alert medications. B. 4, Appendix A: High-Alert Medications...Zemeron (rocuronium). 2. While on tour of facility on 4/18/16 at approximately 1328 hours, accompanied by staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department), high alert medication of Zemeron (rocuronium) was not stored separately from the general medication inventory or in a bin or with a High-alert warning label in the Surgery Department Medication Refrigerator. 3. Staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department) was interviewed on 4/19/16 at approximately 1328 hours and confirmed the above-mentioned high risk/high alert medication was not stored according to policy.	S1022		
S1118	410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8 (b)(2) (b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are	S1118		6/27/16

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S1118	Continued From page 9 assured as follows: (2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees. This RULE is not met as evidenced by: Based on observation, document review and interview, the facility failed to ensure no condition was created or maintained that may result in a hazard to patients, visitors, and/or employees regarding the floor landing above the steps that lead to the basement of Fitness off-site being uneven, off-site storage room located in the basement being heavily cluttered, off-site Therapy Department with assorted fitness equipment stored in the patient restroom, off-site with at least six ceiling light fixtures with their light shielding cracked, broken and missing section of the plastic light cover, hospital Laundry Department folding room ceiling paint chipping and peeling directly above shelves of uncovered folded assorted linen items and without an eyewash station, blanket warmer temperatures being above facility policy guideline for 3 of 3 (Outpatient Department, Medical/Surgical Department and Oncology Department) areas toured; and related to Soiled Utility Rooms not being locked in 5 of 7 (Outpatient/Inpatient Surgical Departments, Medical/Surgical Department, Oncology Department, Alterna Care Extended Care Department) areas toured; and related to clean supplies being stored in Soiled Utility rooms in 2 of 7 (Emergency Department [ED] and Outpatient Surgical Pre/Post Department) areas toured. Findings included:	S1118		

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S1118	Continued From page 10 1. Review of the Safety Plan indicated "Those safety rules and precautions that will be required to provide a safe environment for those entrusted to our care, as well as to all of those who are employed at our facility and to those who may visit have been listed. It is necessary for you to assist in providing a safe and healthful environment." Franciscan Healthcare Rensselaer Safety Plan was last revised June 11, 2013. 2. At 9:13 AM on 4/20/2016, the floor landing above the steps that lead to the basement of Franciscan Health and Fitness off-site was observed to be uneven and posed a trip hazard. The uneven floor surface was visible under the carpet flooring. 3. At 9:15 AM on 4/20/2016, the Franciscan Health and Fitness off-site storage room located in the basement adjacent to the racquetball courts was observed heavily cluttered and unsafe for easy access to assorted equipment. The room was observed with sporting equipment, filled storage boxes and maintenance tools. 4. At 9:20 AM on 4/20/2016, the Franciscan Health and Fitness off-site Therapy Department patient restroom was observed with assorted fitness equipment stored in the restroom that presented uneasy access to the patient's handwashing sink and the toilet. 5. At 9:30 AM on 4/20/2016, Franciscan Health and Fitness off-site was observed with at least six ceiling light fixtures with their light shielding cracked, broken and missing section of the plastic light cover. 6. At 11:20 AM on 4/20/2016, the hospital Laundry Department folding room ceiling paint	S1118		

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S1118	Continued From page 11 was observed to be chipping and peeling directly above shelves of uncovered folded assorted linen items. 7. In interview at 1:15 PM on 4/20/2016, staff member #1 (Director of Operations) confirmed all the above and no other documentation was provided prior to exit. 8. While on tour of facility on: A. 4/18/16 at approximately 1455 hours and 4/19/16 at approximately 1255 and 1426 hours, accompanied by staff 3 (Director of Patient Care Services), it was observed that the blanket warmer temperatures ranged between 134-138 degress Fahrenheit and there was no eyewash station located in the dirty side of the Central Sterile and Reprocessing room or the Maintenance Department. The nearest eyewash station was located in the laundry room, which was approximatelty 100 feet away through 3 doors and various left and right turns. It was a portable eyewash station with 2 bottles of eyewash that expired on 10/2014. B. 4/18/16 at approximately 1400 and 1455 hours, accompanied by staff 3 (Director of Patient Care Services) and staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department), it was observed that: (1). clean supplies of a large plastic tray for cleaning head wounds and toilet paper, tissues and unused trash can liners were stored on open shelving in the ED Soiled Utility Room and soiled instruments are being high-level disinfected in this room as well. (2). new Sani-Cloth wipe containers were stored in closed cabinets in the Outpatient Surgical Pre/Post Department Soiled Utility Room.	S1118		

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S1118	Continued From page 12 (3). Soiled Utility Rooms were unlocked in the Outpatient/Inpatient Surgical Departments, Medical/Surgical Department, Oncology Department and Alterna Care Extended Care Department and contained used sharps containers and used biohazardous bags. 9. Policy #MNT, Eyewash Stations, revised/reapproved on 9/1/15 indicated the eyewash stations must be checked on a regular basis to insure proper delivery of water to adequately flush the eyes of personnel. 10. Policy #IC-26, Inventory, Cleaning, Maintenance of Supplies, Equipment, Medication and Food, revised/reapproved on 8/14 indicated on pg. 1, point II.F., clean or sterile equipment and supplies are to be stored separate from dirty equipment. 11. Policy #IC-11 Infectious Waste/Medical Waste/Refuse, revised/reapproved on 8/14 indicated on pgs. 1 and 2, points 1.a. and 3.b., infectious waste is capable of transmitting dangerous communicable diseases. This includes but is not limited to contaminated sharps or objects that could potentially become contaminated sharps, such as IV (intravenous) spikes...department storage of infectious waste prior to pick-up by Environmental Services shall be stored in a secure area to prevent access by the general public. 12. Staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department) was interviewed on 4/18/16 at approximately 1500 hours and confirmed blanket warmer temperatures have been exceeding the temperature range required per facility policy and	S1118		

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S1118	Continued From page 13 procedure. The eyewash station located in the laundry room had expired eyewash solution. Additionally, Soiled Utility Rooms are not being locked as required per facility policy and procedure, and clean supplies should not be stored in Soiled Utility Rooms to prevent transmission of dangerous communicable diseases.	S1118		
S1160	410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(1) (d) The equipment requirements are as follows: (1) All equipment shall be in good working order and regularly serviced and maintained. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure all equipment is in good working order and regularly serviced and maintained for 1 of 1 (Cryostat) piece of equipment observed. Findings: 1. Review of letter revised/reapproved 12/22/14 related to cryostat confirmed once the pathologist has completed the processing of the frozen section, the Cryostat is to be cleaned of excess tissue/OCT fragments from the interior of the Cryostat to include vacuuming as needed using the Histovac. 2. Review of patient medical records confirmed	S1160		6/2/16

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S1160	Continued From page 14 patient: A. 13 underwent a surgical procedure on 2/22/16 and a frozen section was processed using the Cryostat. B. 14 underwent a surgical procedure on 2/22/16 and a frozen section was processed using the Cryostat. 3. Review of Cryostat maintenance Logs confirmed it was inspected/cleaned last on 10/22/15. 4. Staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department) was interviewed on 4/19/16 at approximately 1328 hours and confirmed Cryostat Maintenance Log was last dated 10/22/15 for inspection and/or cleaning.	S1160		
S1162	410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(2)(A) (d) The equipment requirements are as follows: (2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows: (A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.	S1162		6/3/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	005072	A. BUILDING: _____ B. WING _____	04/20/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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S1162	Continued From page 15 This RULE is not met as evidenced by: Based on document review and interview, the hospital failed to ensure 7 (hydrocollator, scrubber, air handler, 3 wheelchairs and cryostat) of 7 pieces of equipment had preventive maintenance inspections per manufacturer recommendations. Findings included: 1. Review of the Operation Manual instructions for M-2 Master Heating Hydrocollator Unit indicated, "The thermostats are extremely sensitive and the slightest adjustment will alter the temperature several degrees. The recommended operating temperature was 160 to 166 degrees Fahrenheit. The temperature of the water should be checked before using the Steam Packs." 2. Review of Franciscan Health & Fitness offsite therapy Daily Hydrocollator Temperature log for April of 2016 indicated fourteen of fourteen recorded temperatures exceeded 172 degrees Fahrenheit. Review of the hospital in-patient Daily Hydrocollator Temperature log for January through April of 2016 indicated at least 27 days of 74 days the Hydrocollator recorded temperatures were recorded less than 160 degrees Fahrenheit. 3. Review of the Operation Manual Service Schedule for the Saber Compact Walk Behind Scrubber indicated the service schedule required: monthly, 100 hours and 200 hours operating usage for preventive maintenance. 4. Review of the documented preventive maintenance (PM) of the Saber Compact Walk Behind Scrubber indicated the previous three	S1162		

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S1162	Continued From page 16	S1162		

recorded preventative maintenance inspections were: 2/2/16, 7/8/15 and 7/6/14. The recorded preventive maintenance inspections lacked documented monthly, and hour usage preventive maintenance as required by the manufacturer.

5. Review of Preventive Maintenance Air Handler Report stated, "Motor greased every 6 months, filters replaced, belt tension, and coils cleaned as needed."

6. Review of the documented preventive maintenance (PM) of the Air Handler M12606 indicated the previous three recorded preventative maintenance inspections were: 7/6/2014, 6/14/2013 and 4/20/2012. The recorded preventive maintenance inspections lacked documented semiannual preventive maintenance and lacked a preventive maintenance inspection for 2015.

7. Review of the Clinical Engineering Preventive Maintenance schedule indicated the one wheelchair located at Franciscan Health & Fitness offsite and the two wheelchairs located at the Main Entrance of the hospital did not have documented preventive maintenance on them.

8. At 10:20 AM on 4/20/2016, staff member #26 (Clinical Engineer) indicated the wheelchairs are not on the preventive maintenance schedule to have routine inspections performed on them.

9. In interview at 1:15 PM on 4/20/2016, staff member #1 (Director of Operations) confirmed all the above and no other documentation was provided prior to exit.

10. Review of letter revised/reapproved 12/22/14 related to cryostat confirmed once the pathologist

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S1162	Continued From page 17 has completed the processing of the frozen section, the Cryostat is to be cleaned of excess tissue/OCT fragments from the interior of the Cryostat to include vacuuming as needed using the Histovac. 11. Review of patient medical records confirmed patient: A. 13 underwent a surgical procedure on 2/22/16 and a frozen section was processed using the Cryostat. B. 14 underwent a surgical procedure on 2/22/16 and a frozen section was processed using the Cryostat. 12. Review of Cryostat maintenance Logs confirmed it was inspected/cleaned last on 10/22/15. 13. Staff 10 (Director of Operating Room/Post Anesthesia Care Unit/Central Sterile & Reprocessing/Outpatient Department) was interviewed on 4/19/16 at approximately 1328 hours and confirmed Cryostat Maintenance Log was last dated 10/22/15 for inspection and/or cleaning.	S1162		